

Worksheet of Health Services and Situations Eligible for Certificate of Need Review

SUMMARY

(**bold** reviewed in Washington, *italics* referenced in statute)

Proposed to Not Review

Acute Inpatient

Substance abuse (adult)
Substance abuse (child/adolescent)
Intensive care unit (ICU)/Critical care unit
Adult ICU

Long Term Care

Boarding homes (assisted living facility)
Specialty care assisted living facility
Intermediate care mentally retarded facility
Swing beds (>5 beds)
Residential care facility
Psychiatric residential treatment facility
Adult family homes

Medical Equipment

Hyperbaric chambers
Ultrasound
Heart-lung bypass machines

Outpatient Services

Behavioral health services
Opiate replacement treatment facilities (methadone)
Urgent care facilities
Diagnostic imaging centers
Oncology (Cancer) Treatment Centers
Substance Abuse Services
Community clinic

Procedures

Primary/emergent angioplasty
Lithotripsy

Surgery

General Inpatient
Outpatient (hospital)

Other Services

Air ambulance
Information technology
Medical office buildings
Birth Centers

Proposed to Continue Review

Acute Inpatient

Medical-Surgical Licensed Beds
Rehabilitation (Level I)
Psychiatric (licensed)
Obstetrics (Level II & III)
Pediatrics (specialty))
Neonatal ICU (Level II & III)
Burn Units (specialty)
Specialty hospitals (heart, orthopedic, surgical)

Long Term Care

Subacute care (Medicare distinct part)
Long term care hospital
Nursing homes
Contg. care ret. center (5-yr Medicaid life care req)

Medical Equipment

(none)

Outpatient Services

(none)

Procedures

Therapeutic cardiac catheterization
Elective angioplasty
Kidney treatment centers (including hemodialysis)

Surgery

Outpatient (any freestanding ambulatory)
Open heart (adult)
Open heart (pediatric)
Solid organ transplant (adult)
Solid organ transplant (pediatric)
Bone marrow/stem cell transplants
Single-specialty freestanding ambul. surgery centers

Other Services

Home health care (Medicare/Medicaid eligible)
Hospice care centers (inpatient)
Hospice agencies (outpatient, Medicare/Medicaid)

Proposed as New Consideration

Acute Inpatient

Pediatric ICU

Long Term Care

(none)

Medical Equipment

Cyber knives
Computed tomography (CT) scanners
Gamma knives
Magnetic resonance image scanners
Positron Emission Tomography (PET) scanners
PET/CT scanners
Linear accelerators
Robotic Surgery

Outpatient Services

Freestanding emergency departments
Freestanding radiological service centers

Procedures

Diagnostic cardiac catheterization

Surgery

Cardiac
Physician practice office-based surgery

Other Services

Emerging technology and new service categories
Research and demonstration projects

(see the following pages for details)

Worksheet of Health Services and Situations Eligible for Certificate of Need Review

(**bold** reviewed in Washington, *italics* referenced in statute)

| New | Expsn ¹ | NOrv ² | Type of Service | Guiding Principles ⁴ |
|-------------------------------------|-------------------------------------|-------------------------------------|--|--|
| Acute Inpatient | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Medical-Surgical Licensed Beds | <u>specific needs of area, accessibility, impact of new health facilities on expenditures</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Rehabilitation (Level I) | <u>specific needs of area, accessibility, impact of new health facilities on expenditures</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Psychiatric (licensed) | <u>accessibility, affect on facilities for uninsured/underinsured</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Obstetrics (Level II & III) | <u>positive impact on outcomes</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Pediatrics (specialty) | <u>postive impact on outcomes, affect on underinsured and uninsured</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Substance abuse (adult)</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Substance abuse (child/adolescent)</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Intensive care unit (ICU)/Critical care unit</i> | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Neonatal ICU (Level II & III) | <u>data to indicate high quality health care, impact on outcomes</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Adult ICU</i> | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Pediatric ICU</i> | <u>positive impact on outcomes, underinsured/uninsured</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Burn Units (specialty) | <u>specific health needs of area</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Specialty hospitals (heart, orthopedic, surgical) | <u>substantial risk for inappropriate utilization, underinsured/uninsured, total health \$\$</u> |
| Long Term Care | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Subacute care (Medicare distinct part) | <u>accessibility, specific health needs of the area</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Boarding homes (assisted living facility) | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Specialty care assisted living facility | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Intermediate care mentally retarded facility | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Long term care hospital | <u>specific health needs of area, positive impact on outcomes, state funds to cover \$\$</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Nursing homes | <u>specific needs of area, positive impact on outcomes, state funds to cover \$\$</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Swing beds (>5 beds) | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Residential care facility | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Psychiatric residential treatment facility | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Continuing care ret. center (5-yr Medicaid life care req) | <u>specific needs of area</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Adult family homes | |
| Medical Equipment | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Cyber knives</i> | <u>total health expenditures, specific health needs of area, impact on quality outcomes</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Computed tomography (CT) scanners</i> | <u>substantial risk for inappropriate utilization, accessibility</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Gamma knives</i> | <u>total health expenditures, specific needs of area, impact on quality outcomes</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Hyperbaric chambers | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Magnetic resonance image scanners</i> | <u>substantial risk for inappropriate utilization</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Positron Emission Tomography (PET) scanners</i> | <u>substantial risk for inappropriate utilization</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>PET/CT scanners</i> | <u>substantial risk for inappropriate utilization (cumulative radiation,etc)</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Linear accelerators</i> | <u>specific needs of area, state funds to cover increased \$\$</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Robotic Surgery</i> | <u>specific needs of area, state funds to cover increased \$\$</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Ultrasound | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Heart-lung bypass machines | |

¹Expansion

²NO Review of Service

³More information must be considered as qualifiers to some services

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(**bold** reviewed in Washington, *italics* referenced in statute)

| New | Expsn ¹ | NOrv ² | Type of Service | Guiding Principles ⁴ |
|-------------------------------------|-------------------------------------|-------------------------------------|---|---|
| Outpatient Services | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Freestanding emergency departments</i> | <u>affect on underinsured/uninsured, accessibility</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Freestanding radiological service centers</i> | <u>substantial risk for inappropriate utilization, specific needs of area</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Behavioral health services | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Opiate replacement treatment facilities (methadone) | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Urgent care facilities</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Diagnostic imaging centers</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Oncology (Cancer) Treatment Centers</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Substance Abuse Services</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Community clinic | |
| Procedures | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Diagnostic cardiac catheterization</i> | <u>positive impact on quality outcomes, substantial risk for inappropriate utilization</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Therapeutic cardiac catheterization</i> | <u>positive impact on quality outcomes, substantial risk for inappropriate utilization</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Elective angioplasty</i> | <u>positive impact on quality outcomes, substantial risk for inappropriate utilization</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Primary/emergent angioplasty</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Lithotripsy</i> | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Kidney treatment centers (including hemodialysis)</i> | <u>substantial risk for inappropriate utilization, postive impact on qualtiy outcomes</u> |
| Surgery | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Cardiac</i> | <u>substantial risk for inappropriate utilization, postive impact on qualtiy outcomes</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>General Inpatient</i> | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Outpatient (any freestanding ambulatory)</i> | <u>substanital risk for inappropriate utilization, underinsured/uninsured</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Outpatient (hospital)</i> | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Open heart (adult)</i> | <u>accessibility, positive impact on outcomes, data/QI, total health expenditures</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Open heart (pediatric)</i> | <u>accessibility, positive impact on outcomes, data/QI, total health expenditures</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Solid organ transplant (adult)</i> | <u>accessibility, positive impact on outcomes, data/QI, total health expenditures</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Solid organ transplant (pediatric)</i> | <u>accessibiltiy, total health expenditures, data/QI</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Bone marrow/stem cell transplants</i> | <u>accessibiltiy, total health expenditures, data/QI</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Single-specialty freestanding ambul. surgery centers | <u>substantial risk for inappropriate utlization, underinsured/uninsured, total \$\$</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Physician practice office-based surgery</i> | <u>substantial risk for inappropriate utlization, impact on quality and outcomes</u> |
| Other Services | | | | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Home health care (Medicare/Medicaid eligible)</i> | <u>data for QI, substantial risk for inappropriate utilization, specific needs of area</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Hospice care centers (inpatient)</i> | <u>specific needs of area</u> |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <i>Hospice agencies (outpatient, Medicare/Medicaid)</i> | <u>specific needs of area.. state funds to cover increased \$\$</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Air ambulance | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <i>Information technology</i> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Medical office buildings | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Emerging technology and new service categories | <u>total health expenditures, state funds to cover increased \$\$, risk for inappropriate use</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | Birthing Centers | |
| <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | Research and demonstration projects | <u>impact of new health services on quality and outcomes</u> |

¹Expansion

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New **Expsn**¹ **NOrv**² **Type of Service** **Guiding Principles**⁴

General Qualifiers and Considerations from 03/15/06 TAC Meeting:³

1. We need to list the potential or actual state "levers" that exist or need to be strengthened to get the outcomes we want/desire. CON is only one of those levers. The others are Licensure, Accreditation, EMS certification (of Emergency Departments and their levels), and others.
2. We need to recommend how to accomplish the goals of access, cost and quality. For example, the licensure for Emergency Departments should require that they be attached to a "full service" hospital; then there would be no need for a CON for "freestanding Emergency Departments". For imaging, the most important objectives are cost, access and quality. The accreditation "seal" could address the utilization and quality better than reviewing all these imaging purchases through a CON process.
3. The "hot potatoes" that we left unresolved are:
 - a. Imaging: of all types (including nuclear), should they be regulated; if yes, how? In a world of such rapidly changing technology, where the life span of the equipment is longer than the time to "the new, new thing", a ponderous CON process seems inappropriate. The unstated issues for imaging include rapid increases in utilization, hospital vs. free standing, radiology vs. other specialties, ownership, equipment capabilities vs. actual performance of the test (quality of images and quality of interpretation), and patient safety (especially radiation exposure). Rather than deal with the politics, accreditation is a better idea than the CON process.
 - b. Ambulatory surgery of all types including hospital based, freestanding multi-specialty, freestanding single-specialty, and "in office" surgery suites. The "fair treatment" principle may apply: if you do it to one entity, you should do it to the other (what ever "it" may be)
 - c. Radiation therapy including linear accelerators, cyber knives, gamma knives, proton beam, brachytherapy and others. Licensure and Accreditation seem more relevant.
 - d. Emerging technologies and research.
4. The two most important criteria for "what's included in CON" are:
 - a. Maintaining the fragile state-wide publicly-funded hospital infrastructure (so something that would remove 20% of revenues and impact the functioning of a hospital would be a concern, while some service that impacted less than 3% of revenues [as an example] would not be a concern, just the changes in health care over time).
 - b. Regionalizing a very limited number of services that are low-volume, high-risk, high-cost and require complex multi-specialty interactions (solid organ transplantation and pediatric complex cases are examples).
5. Because of the potential impact on total expenditures as well as the potential impact on quality outcomes (including issues like exposure risk), major pieces of medical equipment needed to be considered for inclusion in the scope of coverage of a CON program.
6. There are concerns that new facilities be reviewed to determine whether they will be serving Medicaid consumers (and perhaps Medicare), what their charity care policies are, and the kinds, quality and amount of other health-related community benefit activities they might provide. For long term care facilities like nursing homes and ICF-MR facilities, there should be some consideration of the availability of community-based alternatives, such as through the Medicaid Home and Community Based Waiver programs before approval is granted.
7. There is no column to reflect "community benefits" or "community health outcomes review," which is different from licensure or accreditation and properly part of CON. Certificate of Need currently considers charity care provision (at least related to hospitals - see RCW 70.38.115), and if CON is going to be linked to community health outcomes and statewide planning, then all new facilities should at least submit information about how they will impact community health outcomes through at least the above considerations. This kind of review should also be included in the full-blown CON review.
8. We must be sure we would take into account the impact on home health and home care agencies that are not state-contracted, but who provide in-home services. HCBW programs are separate from In-Home services programs, but do have some overlap. Regarding new ICF of SNFs, both the waiver programs and other in-home services programs would impact the need for new facilities.
9. Mention was made of licensure and certification requirements, and how they overlap or don't overlap the CON process; they mostly don't. There are things in the CON requirements that are never looked at in the licensure surveys. Except for a requirement in the Medicare Hospice regulations for the use of volunteers at a specified number of hours and the requirement that care not be denied for inability to pay, there is no other regulatory requirement in the In-Home Services arena that licensure staff would review regarding charity care. The same can be said regarding access. A Medicare-certified agency (home health or hospice) could specify they will cover Xyz County, but for whatever reason doesn't, and this will not ever become part of the licensure survey process.
10. Level IIa Obstetrics/Neonatal services should not be reviewed. If the Perinatal Guidelines (2005 developed) were codified and a differentiation were made in the CON application and approval process to differentiate "a" from "b" in the Levels, then these could be separated in the consideration and application process. Also, because they do not currently differentiate the "a" from the "b" in Level II (or Level III for that matter), it is not "clear" what capability a particular facility has and should be held accountable to during licensure review and other processes.

¹Expansion

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(**bold** reviewed in Washington, *italics* referenced in statute)

| <u>New</u> | <u>Expsn¹</u> | <u>NOrv²</u> | <u>Type of Service</u> | <u>Guiding Principles⁴</u> |
|------------|--------------------------|-------------------------|------------------------|---------------------------------------|
|------------|--------------------------|-------------------------|------------------------|---------------------------------------|

Statutory Guiding Principles:⁴

The Task Force is to be guided by considering the following principles:

1. Impact of the supply of health services on utilization.
2. Effect of new health services/facility on expenditures.
3. Impact of new health facilities/services/equipment on quality and outcomes.
4. Current coverage of facilities and services is to remain.

The Task Force is to develop criteria, including consideration of:

1. Public Need:
 - a) Specific health needs of an area
 - b) Positive impact on health indicators of population served
 - c) Substantial risk for inappropriate utilization
 - d) Accessibility for all residents
 - e) Data to indicate QI
2. Impact on orderly economic development of health facilities and health resources:
 - a) Impact on total health expenditures
 - b) Affect on existing providers and facilities service for underinsured/uninsured
 - c) Availability of state funds to cover increased cost
 - d) Potential of more effective or accessible or less costly alternatives

(literal quotes from ESSHB 1688)

Sec. 3.1. In conducting the certificate of need study and preparing recommendations, the task force shall be guided by the following principles:

- (a) The *supply of a health service can have a substantial impact on utilization* of the service, independent of the effectiveness, medical necessity, or appropriateness of the particular health service for a particular individual;
- (b) Given that health care resources are not unlimited, *the impact of any new health service or facility on overall health expenditures in the state must be considered*;
- (c) Given our increasing ability to undertake technology assessment and measure the quality and outcomes of health services, the *likelihood that a requested new health facility, service, or equipment will improve health care quality and outcomes must be considered*; and
- (d) It is *generally presumed that the services and facilities currently subject to certificate of need should remain subject to those requirements*.

Sec. 3.2. The task Force shall, at a minimum, examine and develop recommendations related to the following issues: . . .

- (d) The criteria for review of certificate of need applications, as currently defined in RCW 70.38.115, with the goal of having criteria that are consistent, clear, technically sound, and reflect state law, including consideration of:
 - (i) *Public need for the proposed services* as demonstrated by certain factors, including, but not limited to:
 - (A) Whether, and the extent to which, the project will substantially *address specific health problems as measured by health needs in the area to be served by the project*;
 - (B) Whether the project will have a *positive impact on the health status indicators of the population to be served*;
 - (C) Whether there *is a substantial risk that the project would result in inappropriate increases in service utilization or the cost of health services*;
 - (D) Whether the services affected by the project *will be accessible to all residents of the area proposed to be served*; and
 - (E) Whether the project *will provide demonstrable improvements in quality and outcome measures applicable to the services proposed in the project, including whether there is data to indicate that the proposed health services would constitute innovations in high quality health care delivery*;
 - (ii) *Impact of the proposed services on the orderly and economic development of health facilities and health resources for the state* as demonstrated by:
 - (A) The *impact of the project on total health care expenditures* after taking into account, to the extent practical, both the costs and benefits of the project and the competing demands in the local service area and statewide for available resources for health care;
 - (B) The *impact of the project on the ability of existing affected providers and facilities to continue to serve uninsured or underinsured residents of the community and meet demands for emergency care*;
 - (C) The *availability of state funds to cover any increase in state costs* associated with utilization of the project's services; and
 - (D) The *likelihood that more effective, more accessible, or less costly alternative technologies or methods of service delivery may become available*;

¹Expansion

²NO Review of Service

³More information must be considered as qualifiers to some services